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April 12, 2023

VIA CM/ECF

Honorable Lorna G. Schofield
United States District Court
Southern District of New York
500 Pearl Street
New York, NY 10007

Re: *Teva Pharmaceuticals USA, Inc. v. Perrigo, LLC, et al.*, No. 1:23-cv-01825-LGS

Dear Judge Schofield:

In accordance with Your Honor's March 6, 2023 Initial Conference Order (ECF No. 7), Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") and Defendants Perrigo, LLC ("Perrigo LLC") and Perrigo Pharma International D.A.C. ("PPIDAC") submit this joint letter in advance of the Fed. R. Civ. P. 16 conference scheduled for April 19, 2023.

(1) Nature of the Case

A. Plaintiff

Teva's claims against Perrigo and PPIDAC (collectively, "Perrigo") allege breaches of a contract between Teva and Perrigo ("Agreement") governing the purchase and sale of generic, over-the-counter versions of Fexofenadine HCl pharmaceutical products ("Fexo"). The Agreement provided for Teva to manufacture and sell Perrigo bulk Fexo product and for Perrigo to package the bulk product into finished Fexo product for marketing in the United States.

The parties explicitly agreed that Teva would charge, and Perrigo would pay, a purchase price based on Teva's Fully Absorbed Costs as determined in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). In order to comply with the Agreement, Teva initially charged Perrigo a price based on Teva's estimated costs at the time of the shipment of Fexo because precise actual absorbed costs are indeterminable at the time of manufacture and supply. Pursuant to US GAAP absorption cost accounting rules, Teva's actual Fully Absorbed Costs could only be determined at a later time.

Accordingly, the pricing mechanism under the Agreement required Teva and Perrigo to participate in a periodic "true up" process whereby Teva would reimburse Perrigo for any payments made pursuant to initial pricing that was based on estimated costs which exceeded Teva's actual Fully Absorbed Costs, as later determined; and Perrigo, correspondingly, would compensate Teva if it paid prices based upon estimated costs that were later determined to be less than Teva's actual Fully Absorbed Costs. Because the Agreement obligated Perrigo to pay

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for Fexo at a price based on Teva's Fully Absorbed Costs, a true-up process was the only accounting mechanism by which Teva could calculate its Fully Absorbed Costs and by which Perrigo could be charged the agreed-to pricing structure.

Despite Teva reimbursing Perrigo when its actual Fully Absorbed Costs were less than the estimated costs used for the initial pricing between 2014 and 2016, Perrigo now refuses to compensate Teva for true-up amounts from 2017–2019,¹ when Perrigo paid initial pricing based on estimated costs that were less than Teva's actual Fully Absorbed Costs for that period.

Moreover, Teva alleges Perrigo has committed additional breaches of the Agreement by refusing to pay at all for certain Fexo batches ordered from Teva. Pursuant to the Agreement, Perrigo issued to Teva various twelve-month rolling forecasts of its anticipated demand of Fexo along with binding purchase orders for Fexo. In response to these forecasts and purchase orders, in accordance with its obligations under the Agreement, Teva obtained active pharmaceutical ingredients ("API") and other materials for use in the manufacture of Fexo, and for certain binding purchase orders, Teva actually manufactured batches of Fexo for Perrigo.

Nevertheless, on or about March 26, 2021, Perrigo cancelled certain binding purchase orders, and then on or about June 1, 2021, Perrigo unilaterally terminated the Agreement and purportedly "cancelled" all remaining binding purchase orders. Despite the Agreement plainly obligating Perrigo to pay for binding purchase orders (i.e., those purchase orders issued by Perrigo and accepted by Teva) notwithstanding its unilateral cancellation of the purchase orders or its unilateral termination of the Agreement, Perrigo refuses to compensate Teva for:

- (a) Fexo batches manufactured by Teva for binding purchase orders not cancelled;
- (b) Materials for Fexo batches not manufactured by Teva for binding purchase orders not cancelled;
- (c) Materials for Fexo batches not manufactured by Teva for binding purchase orders purportedly cancelled; and
- (d) API and other materials Teva purchased to fulfill Perrigo's 2021 forecast.

B. Defendants

This case involves a 2010 agreement (the "Term Sheet") for the purchase and sale of Fexo entered into by Teva and Perrigo LLC, which was assigned to PPIDAC in March 2020. Teva's claims are without merit.

First, Teva claims that Perrigo failed to pay what it has called "true-up" amounts. Put simply, these "true-up" amounts reflect subsequent, higher invoices that Teva issued for product that Perrigo had already paid for in full. The Term Sheet does not include any so-called "true-up" right or process. The parties agreed that Perrigo LLC would purchase Fexo from Teva based on a

¹ On November 29, 2021, Teva and Perrigo executed a Tolling Agreement pursuant to which the parties agreed to toll the running of any applicable statutes of limitations while the parties engaged in mediation. The Tolling Agreement was terminated on or about January 26, 2023, and Teva initiated this action on January 31, 2023.

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“Transfer Price,” which under § 5 of the Term Sheet means Teva’s “Fully Absorbed Costs...plus five percent (5%) of such Fully Absorbed Costs.” In turn, the definition of “Fully Absorbed Costs” in Schedule 1 states only that the actual costs required for the production, packaging and labeling of Fexo are to be determined in accordance with generally accepted accounting principles (“GAAP”). Tellingly, the parties knew how to—and did—provide for a “true-up” process when they wanted one. Under the Term Sheet, a portion of “Net Sales,” a separate and unrelated amount to this dispute, would include an “estimate[] in accordance with U.S. GAAP” for product returns “provided that to the extent actually incurred or accrued, such accrual will be true-up on a quarterly basis.” The parties did not include such a true-up provision with regard to determining either the Transfer Price or Fully Absorbed Costs, and the contract is unambiguous and speaks for itself.

Second, Teva claims Perrigo breached the Term Sheet when it failed to pay Teva for non-binding forecasts (subsection (d) of Teva’s statement above), even though the contract unambiguously states that such forecasts are “non-binding.”

Third, all of Teva’s unjust enrichment and promissory estoppel claims are improper because there is a valid, governing contract that covers the matters in dispute. Teva also fails to properly allege the elements of these claims, in any event.

Fourth, regarding subsections (a)-(c) of Teva’s statement above, Perrigo is not responsible for any claimed damages because the evidence will demonstrate that Fexo product Teva had delivered failed to meet contractual and/or regulatory specifications, that Teva’s own testing confirmed such failures were a result of Teva’s manufacturing processes, and that Teva did not cure such processes during the period of its claims—making the Fexo at issue therefore unsaleable.

Finally, part of Teva’s “true-up” claims are time-barred as Teva had four years to commence litigation. Here, Teva alleges that it first demanded payment for true-up amounts in 2017-18 in February 2018, nearly five years prior to filing this Complaint.²

(2) Basis of Subject Matter Jurisdiction and Venue (Joint Statement)

The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because Teva has diverse citizenship from Perrigo LLC and PPIDAC and the amount-in-controversy exceeds \$75,000. There is also venue pursuant to 28 U.S.C. § 1391 because, among other things, Perrigo LLC and PPIDAC contractually consented to this venue in the Agreement.

(3) Factual Basis for Diversity of Citizenship Jurisdiction (Joint Statement)

First, Teva is a Delaware corporation with its principal place of business in New Jersey.

² The parties’ tolling agreement is unenforceable because it does not contain a fixed termination date. See N.Y. Gen. Oblig. § 17-103.

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Second, PPIDAC is an Irish company with its principal place of business in Ireland.

Finally, Perrigo LLC is a Delaware limited liability company. Perrigo LLC's sole member is Perrigo Israel Trading Limited Partnership. Perrigo Israel Trading Limited Partnership has two partners: Perrigo International Holdings, LLC and Perrigo Global Holdings, Inc. Perrigo International Holdings LLC's sole member is Perrigo International Holdings, Inc., a Michigan corporation with its principal place of business in Michigan. Perrigo Global Holdings, Inc. is also a Michigan corporation with its principal place of business in Michigan. Therefore, Perrigo LLC is a citizen of Michigan.

(4) Motions

A. Plaintiff

To the extent discovery shows there is no genuine dispute of material fact, Teva intends to move for summary judgment on its true-up claims and its unpaid purchase order claims.

B. Defendants

First, Defendants intend to file a partial motion to dismiss most of Teva's claims for: (1) alleged "true-up" payments; (2) damages related to "API and other materials Teva purchased to fulfill Perrigo's 2021 forecast;" (3) unjust enrichment claims; and (4) promissory estoppel claims.

Second, given the wide-ranging scope of the motion to dismiss and the potential impact the Court's resolution of that motion may have on both scope and timing of discovery (which will include discovery from foreign entities and witnesses), Defendants also intend to seek a stay of discovery pending the Court's resolution of the motion.

Finally, in addition to any issues that remain after the motion to dismiss, Perrigo also intends to bring a motion for summary judgment to address the non-conforming Fexo at issue (for which Perrigo is not required to pay Teva), to the extent that discovery shows there is no genuine dispute of material fact.

(5) Discovery (Joint Statement)

Teva and Perrigo LLC have already engaged in a limited document exchange in advance of a previously held mediation session. If a stay of discovery is not granted pending Perrigo's motion to dismiss, the parties anticipate engaging in written discovery, document discovery and depositions to be held on topics including, but not limited to: the Agreement's pricing mechanism and the status of payments under the contract; the parties' course of conduct relating to Fexo pricing; the 2021 forecast and the status of any purchase orders; PPIDAC's termination of the Agreement; Fexo manufacturing, quality investigations, and testing; Teva's costs of manufacturing Fexo; and Teva's efforts to mitigate alleged losses. The parties anticipate

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exchanging ESI discovery and will negotiate an ESI discovery stipulation and confidentiality agreement.

The parties anticipate expert discovery, including on forensic accounting, damages, product testing and/or regulatory issues.

(6) Computation of Damages (Plaintiff)

Teva seeks the following damages, exclusive of interest:

1. True-up payments:	\$6,183,925.00
2. Unpaid purchase orders for manufactured Fexofenadine:	\$8,099,465.45
3. Materials for additional Fexofenadine batches ordered and not cancelled:	\$5,953,500.00
4. Materials for additional Fexofenadine batches ordered and purportedly cancelled:	\$3,817,012.50
5. API and other materials Teva purchased to fulfill Perrigo's 2021 forecast:	\$9,343,502.00
Total:	\$33,397,404.95

(7) Status of Settlement Discussions (Joint Statement)

On December 12, 2022, Teva and Perrigo LLC participated in a mediation session with the Hon. Morton Denlow (Ret.). As noted above, the parties engaged in a limited document exchange. Teva and Perrigo LLC did not reach a settlement and the parties agree that further settlement discussions would not be productive at this time.

Respectfully submitted,

/s/ Joseph E. Wolfson

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Respectfully submitted,

/s/ Diana Sterk

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 Perrigo Pharma International D.A.C.*

cc: All counsel record (via CM/ECF)